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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/314,919 05/19/99 MICHEL

W 6464

EXAMINER

QM22/0829

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ART UNIT	PAPER NUMBER

3761

DATE MAILED:

08/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.
09/314,919

Applicant(s)
Michel

Examiner
David J. Cho

Group Art Unit
3761



☒ Responsive to communication(s) filed on Jun 19, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-24 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-24 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 6, 8, 10-13, 15-19, 21, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ensminger et al. '5,281,199.

Ensminger discloses a permanently implantable access device comprising, a port body 72 implanted subcutaneously, providing for the delivery of substances and for the removal of body fluids for analysis, a shaft section 80, a mounting platform 98 that is generally disc-shaped, a valve 84 that is self-closing, two tubes 94, 96 extending into the interior of the body that serve as a feed tube and an aspiration tube, catheters received into said tubes, and a sensing device inserted into the interior of the body via the port body. (See figures 3-6, 1:21-28, 1:50-57, 3:58-4:3, 8:61-9:2 & 9:43-10:21). Moreover, in regards to the self sealing diaphragm, Ensminger clearly teaches the leaflet valve elements 38 and 40 to reseal, wherein removal of the external filament 46, valve 24 returns to its normal closed condition, see column 8:61 through 9:2. In regards to the newly added claims (19-24), Ensminger teaches the device may be used with sutures or surgical staples with the device, e.g., sutures and staples are considered anchor members.

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Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ensminger et al. in view of Patsalos et al. '5,607,390.

Ensminger discloses all the elements of the applicant's invention except for the microdialysis probe. Patsalos discloses a microdialysis probe that can be left inside the body for an extended period of time for continuous testing and that can be positioned in different locations inside the body for fluid analysis wherein body fluids can be withdrawn. Ensminger discloses the use of sensing and physiological measuring devices in combination with their access device. The microdialysis probe disclosed by Patsalos et al is a physiological measuring device that is inserted into a cannula or access device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention to use Patsalos et al microdialysis probe in combination with Ensminger access device for analyzing body fluids.

In regards to claims 20, 22 and 24, it would have been an obvious matter of design choice to modify the anchor to a generally disc shape, since such a modification would have involved a mere change in the shape of a component. A change in size or shape is generally recognized as being within the level of ordinary skill in the art.

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Response to Arguments

5. Applicant's arguments filed 6/16/00 have been fully considered but they are not persuasive.

In response to applicant's argument that the device of Ensminger and the present invention function in two different ways is found non-persuasive. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Moreover, it is the examiner's position that the device Ensminger clearly teaches a self sealing diaphragm, see paragraph 2 of this Office Action.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is in the knowledge generally available to one of ordinary skill in the art to combine the microdialysis probe with Ensminger for analyzing body fluids.

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In response to applicant's argument that Patsalos discloses a dialysis probe for insertion into the body, the fact that applicant uses the probe for a different purpose does not alter the conclusion that its use in a prior art device would be prima facie obvious from the purpose disclosed in the reference.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Conclusion

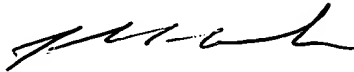
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,337,756, 5,286,453, 5,033,476 discloses various other devices that provides a self-sealing diaphragm.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Cho whose telephone number is (703) 308-0073. The Examiner can normally be reached on Monday-Friday from 9:00 am to 5:00 pm.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0585.

dj cho

Patent Examiner
August 25, 2000


John G. Weiss
Supervisory Patent Examiner
Group 3700